



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,209	04/20/2006	Julie Hazel Campbell	4501-1016	9620

466 7590 05/19/2010
YOUNG & THOMPSON
209 Madison Street
Suite 500
Alexandria, VA 22314

EXAMINER

TSAY, MARSHA M

ART UNIT	PAPER NUMBER
----------	--------------

1656

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

05/19/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No. 10/530,209	Applicant(s) CAMPBELL ET AL.	
	Examiner Marsha M. Tsay	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,5-10,12,17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,5-10,12,17 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1656

This Office action is in response to Applicants' remarks received March 1, 2010.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Claims 1-2, 4, 11, 13-16, 19-24 are canceled. Claims 3, 5-10, 12, 17-18 are currently under examination.

Priority: The request for priority to NEW ZEALAND 521955, filed October 4, 2002, is acknowledged.

Objections and Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1656

Claims 3, 5-10, 12, 17-18 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over McLachlan (US 20020166129; previously cited). For examination purposes, the instant claims have been interpreted as: a method for treating hypercholesterolemia or hyperlipidemia in a mammal comprising orally administering to said mammal a composition comprising β -casein where the β -casein is comprised of at least 95 wt% β -casein A².

The applied reference has 1 common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

McLachlan teaches a method of treating coronary heart disease in a human which comprises that the human ingests a milk having greater than 95% by weight of β -casein A² (p. 11 claim 1-6; claim 3, 5-10, 17). The milk is obtained from bovines (p. 11 claim 2; claim 12). McLachlan further teaches that the milk comprises approximately 100% by weight of β -casein A² (p. 11 claim 7; claim 3). The milk composition comprising β -casein A² can also contain additional supplements or be in the form of a powder (p. 4 [0089-0091]; claims 7-8, 18).

On page 3 [0066], McLachlan teaches that coronary heart disease means any disease or disorder relating to the coronary heart system and includes atherosclerosis.

Therefore, it would have been obvious to one of ordinary skill to know that disorders relating to the coronary heart system would include high cholesterol and high lipid levels, even if

Art Unit: 1656

not explicitly taught by McLachlan and therefore one of ordinary skill would be motivated to administer a milk having greater than 95% by weight of β -casein A² to a mammal for treating disorders relating to the coronary heart system, i.e. high cholesterol levels and high lipid levels.

Firstly, it should be noted that the previous Office action (p. 2) inadvertently cited the incorrect statement of statutory basis for the 35 U.S.C. 102(e) rejection. The 35 U.S.C. 103(a) quotation was inadvertently cited instead when it should have been the 35 U.S.C. 102(e) quotation, instead. The instant action correctly states the appropriate statements of statutory basis for prior art rejections.

In their remarks received March 1, 2010, Applicants' assert that (1) McLachlan pertains to milk and milk products for preventing or treating heart disease. McLachlan does not teach or suggest in any way the treatment of hypercholesterolemia or hyperlipidemia. McLachlan teaches the treatment of coronary heart disease, but this is not the same thing as the treatment of hypercholesterolemia or hyperlipidemia, despite the possibility of hypercholesterolemia or hyperlipidemia being contributing factors to heart disease. (2) For example, atherosclerosis is a disease of large and medium-sized muscular arteries. Atherosclerosis is characterized by plaque formation, vascular remodeling, acute and chronic luminal obstruction, abnormalities of blood flow, and diminished oxygen supply to target organs. In contrast, hyperlipidemia means that the patient has high cholesterol and high triglyceride levels. Similarly, hypercholesterolemia means high cholesterol in the blood. (3) Although hypercholesterolemia or hyperlipidemia may be a contributing factor to atherosclerosis, it does not follow that a treatment for hypercholesterolemia or hyperlipidemia will be an effective treatment for atherosclerosis and

Art Unit: 1656

vice versa. For example, stents for vascular surgery may be used to treat atherosclerosis, but these treatments would have no effect on hypercholesterolemia or hyperlipidemia. On the other hand, reducing cholesterol or lipid levels may not affect an already damaged vascular structure.

Applicant's arguments have been fully considered but they are not persuasive.

(1) Response: As also noted by Applicants', McLachlan teaches that coronary heart disease is intended to mean any disease or disorder relating to the coronary heart system (McLachlan p. 3 [0066]). Since one of ordinary skill would know that disorders relating to the coronary heart system can include hypercholesterolemia or hyperlipidemia, even if not explicitly stated by McLachlan, it would be reasonable for one of ordinary skill to know that said milk having greater than 95% by weight of β -casein A² can be administered to treat hypercholesterolemia or hyperlipidemia since these are disorders relating to the coronary heart system (further evidenced in the art by Schaefer 2002 Am J Clin Nutr 75: 191-212, see specifically p. 191).

(2) Response: As noted in the response to (1) above, atherosclerosis, hypercholesterolemia or hyperlipidemia are all disorders that would be related to the coronary heart system.

(3) Response: The rejection of the instant claims has been changed from a 102(e) rejection to a 102(e)/103(a) rejection. Therefore, even if a treatment for atherosclerosis may not be effective for hypercholesterolemia or hyperlipidemia and vice versa, one of ordinary skill would still be motivated to administer said milk having greater than 95% by weight of β -casein A² for treating disorders related to the coronary heart system since McLachlan teach that a milk having greater than 95% by weight of β -casein A² can be administered to a mammal for treating

Art Unit: 1656

disorders related to the coronary heart system. Further, even if not explicitly taught by McLachlan, one of ordinary skill would know that disorders relating to the coronary heart system can include hypercholesterolemia (evidenced by Schaefer p. 191).

For at least these reasons, the McLachlan reference is maintained.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

Art Unit: 1656

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

May 12, 2010

M. Tsay
Art Unit 1656